Addendum to the FDA Background Document for the January 24-25, 2013 Drug Safety and Risk Management Advisory Committee Meeting

January 24-25, 2013 Meeting Overview

Please note that the Addendum to the FDA Background Document may include references to the originally scheduled Drug Safety and Risk Management Advisory Committee meeting which was to take place on October 29-30, 2012. This originally scheduled meeting was postponed and rescheduled for January 24-25, 2013 due to unanticipated weather conditions caused by Hurricane Sandy.

The Department of Health and Human Services (HHS) received a request from the Drug Enforcement Administration (DEA) for a scientific and medical evaluation and scheduling recommendation for drugs containing hydrocodone either combined with other analgesics or as an antitussive, in response to a citizen petition citing increasing reports of abuse related to these products. Currently, these products are Schedule III drugs under the Controlled Substances Act (CSA), and DEA is considering whether to reschedule the products to Schedule II, which would subject the products to more stringent requirements regarding storage, record keeping, and prescribing, such as limitations on oral prescriptions and refills.

In making a determination on whether to control or reschedule a drug, the DEA must consider 8 factors: (1) the drug's actual or relative potential for abuse, (2) scientific evidence of its pharmacological effect, if known, (3) the state of current scientific knowledge regarding the drug or other substance, (4) its history or current pattern of abuse, (5) the scope, duration, and significance of abuse, (6) what, if any, risk there is to the public health, (7) its psychic or physiological dependence liability, (8) whether the substance is an immediate precursor of a substance already controlled under this title.

Before proceeding to control or reschedule a drug under this process, DEA asks the Secretary of HHS for a scientific and medical evaluation of the drug and for a recommendation as to whether (and under what schedule) the drug should be controlled. FDA is delegated the responsibility for preparing the documentation to schedule or reschedule a drug. FDA, with the concurrence of the National Institute on Drug Abuse (NIDA/NIH) provides this information to the Assistant Secretary for Health (ASH), based on scientific and medical considerations associated with the 8 factors.

On October 29 and 30, 2012, FDA's Drug Safety and Risk Management Advisory Committee will discuss the potential for abuse, including public health related issues, of hydrocodone combination products. In advance of the meeting, FDA staff prepared a 363-page briefing memo for the committee to provide data intended to inform the committee's discussion on four questions: whether the pharmacology and epidemiological data is sufficient to demonstrate that abuse potential is equal to schedule II products, whether they have recommendations for implementing approaches to reduce abuse and misuse; the impact of rescheduling on appropriate patient access, and finally whether the product should be rescheduled.

FDA is looking forward to the advisory committee meeting as an opportunity to continue the dialogue over how to balance access to these important pain medications with appropriate controls to deter misuse and abuse and to obtain additional scientific data and analysis on whether to reschedule hydrocodone combination products.

The advisory committee of outside experts will provide FDA with an independent opinion and recommendation about whether hydrocodone products should be rescheduled to schedule II of the CSA. The advisory committee's decision will inform FDA's ultimate recommendation to the Assistant Secretary of Health, but the agency will not be making any decisions during the meeting.